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Patent Document 3: Japanese Unexamined Patent Application

Publication No. 2002-331025

Patent Document 4: Japanese Unexamined Patent Application

Publication No. 2003-126236

Patent Document 5: PCT Japanese Translation Patent

Publication No. 2003-532466

### Disclosure of Invention

#### Problems to be Solved by the Invention

In the methods of reconstructing an ocular surface using an amnion disclosed in the above patent documents, transplantation is performed using the whole amnion on which epithelial stem cells and epithelial cells proliferated from the epithelial stem cells are adhered.

However, a transplant in which such an amnion is used as a substrate has a thickness of less than 100 µm and does not have a layer corresponding to the stroma. Therefore, such a transplant is fragile in view of strength. Although such a transplant is suitable for reconstruction of an ocular surface, it is not suitable for transplantation that requires a transplant with a certain thickness including the stroma. In cases where the lesion extends to the stroma, a further improvement is desired in the transplantation method using an amnion.

It is an object of the present invention to provide a medical material that improves therapeutic effects in

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epithelial cells such as keratoconjunctival epithelial cells with the use of an amnion, and a process for producing the same.

### Means for Solving the Problems

In order to achieve the above object, the present inventors have found that when epithelial stem cells are cultured on the surface of an amnion that is bonded and crosslinked with a biocompatible polymer film, a medical material including the biocompatible polymer film, the amnion, the epithelial stem cells, and epithelial cells proliferated from the epithelial stem cells so as to cover the amnion and to form a single layer can be obtained.

Namely, the present invention provides a material for reconstructing an ocular surface to be transplanted on an affected part where not only epithelial cells but also their stem cell tissue is eradicated or damaged, the material including an amnion, which is a placental tissue; a clear biocompatible polymer film bonded to one surface of the amnion and crosslinked with covalent bonds; and corneal epithelial cells, corneal stromal cells, corneal endothelial cells, or conjunctival epithelial cells that are adhered to the other surface of the amnion.

The present invention also provides a process for producing the material for reconstructing an ocular surface including the steps of preparing an amnion from which the

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spongy layer is removed, bonding a biocompatible polymer film to one surface of the amnion followed by crosslinking, adhering epithelial stem cells to the other surface of the amnion, and proliferating epithelial cells from the epithelial stem cells on the surface of the amnion.

### Advantages of the Invention

Since a biocompatible polymer film has high biocompatibility, after a transplant is transplanted, the survival rate is increased compared with the case where a biocompatible polymer film is not used. Furthermore, since a biocompatible polymer film is clear and the thickness of the film can be appropriately changed, the biocompatible polymer film is particularly effective for the transplantation of the corneal epithelium or the conjunctival epithelium and the stroma.

Furthermore, by culturing epithelial stem cells on an amnion that is bonded and crosslinked with a biocompatible polymer film in advance, advantageously, handleability is improved and suturing can be easily performed. The film can be applied to an artificial cornea by immobilizing the corneal epithelium alive on one side of the film and the corneal endothelium alive on the other side of the film.